

Remarks

Applicants have reviewed the Final Office Action mailed February 22, 2011. Prior to entry of this amendment, claims 1-13, 16-37, and 39-51 are pending. By this amendment, claims 1-3, 7, 8, 11, 13, 16-18, 20, 22, 23, 30-32, 34, 39, 40, 45, and 51 are amended, claims 4-6, 9, 10, 12, 14, 15, 21, 24, 25, 27, 28, 33, 35-38, 41-44, and 46-50 are cancelled without prejudice or disclaimer of the subject matter therein, and new claims 52-75 are added. Applicants respectfully submit the following remarks.

Objections to the Claims

In the Final Office Action, the Examiner objected to claims 17 and 18 as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, the Examiner noted that claims 17 and 18 “are substantially duplicate claims.” Final Office Action, p. 2, line 7. Applicants respectfully disagree and traverse the objection. As previously presented, claim 17 provided for storing the neurological data by the external component, while claim 18 included sending the neurological data to an external site. In addition, Applicants have amended claims 17 and 18 to provide further clarity regarding the claimed aspects of the invention. Accordingly, Applicants respectfully submit that claims 17 and 18 provide different scopes of protection and thus are in proper dependent form. Applicants respectfully request the Examiner withdraw the objection.

Claim Rejections under 35 U.S.C. § 103

Claims 1-13, 16-19, 21-32, 35-37 and 39-51 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent Application No. 2002/0013612 to Whitehurst (“Whitehurst”) in view of U.S. Patent No. 5,154,172 to Terry, Jr. et al. (“Terry”). Claim 20 stands rejected under § 103(a) over Whitehurst in view of Terry and further in view of U.S. Patent Application Publication 2002/0013613 to Haller et al. (“Haller”).

Applicants respectfully traverse the rejections. While Applicants disagree with the Examiner’s rejections, the claims have been amended as presented above in an effort to more quickly advance prosecution toward allowed subject matter. No admission should be inferred by these amendments, and Applicants reserve the right to prosecute the originally filed and previously presented claims in future prosecution. Support for the amendments and new claims

can be found throughout Applicants' originally-filed application, including at least in paragraphs [179]-[185] on pages 58-62.

In a proper obviousness analysis, "the scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545. "[T]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985); see also MPEP 706.02(j). In other words, "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR International Co. v. Teleflex Inc.* (*KSR*), 550 U.S. 398, 418, 82 USPQ2d 1385 at 1396 (2007) (quoting *In re Kahn* with approval).

To the extent the current rejections may apply to the amended and new claims, Applicants respectfully traverse the rejections and submit that Whitehurst, Terry, and Haller, alone or in combination, do not disclose or otherwise suggest all of the limitations of the claims. In addition, Applicants respectfully submit that there is no convincing line of reasoning for a finding of obviousness in place of the undisclosed limitations.

Independent Claim 1

Like previously presented claim 1, amended independent claim 1 is directed to a medical device system for treating a nervous system disorder. Among other features, amended claim 1 provides for an implantable component that operates in a first treatment therapy mode, and an external component. Summarizing, amended claim 1 also provides that the implantable component operates according to a second treatment therapy mode if the presence of the external component is detected, but stops operating according to the second mode if it detects that the external component is not present. Claim 1 is presented below as it stands after the present amendment:

1. A medical device system that provides treatment therapy for a nervous system disorder, comprising:

an implantable component configured to be implanted within a patient body and operate according to a first treatment therapy mode; and

a first external component configured to be positioned external to the patient body, generate a signal indicating the presence of the first external component to the implantable component, and provide a second treatment therapy mode;

the implantable component further configured to receive the signal from the first external component and detect that the first external component is present based on receiving the signal,

the implantable component further configured to detect that the first external component is not available based on not receiving the signal,

the implantable component further configured to begin operating in conjunction with the first external component according to the second treatment therapy mode if the implantable component detects that the first external component is present, and

stop operating according to the second treatment therapy mode if the implantable component detects that the first external component is not present.

In the Final Office Action, the Examiner noted that Whitehurst does not disclose all the limitations of claim 1, but relied on Terry to argue that claim 1 was obvious in view of the combination of Whitehurst and Terry. Applicants traverse the rejection to the extent the rejection may still apply to amended claim 1. For example, Applicants respectfully submit that the combination of Whitehurst and Terry at least does not disclose

- a medical device system comprising an implantable component and a first external component,
- the implantable component configured to begin operating according to a second treatment therapy mode if it detects that the first external component is present, and
- the implantable component configured to stop operating according to the second treatment therapy mode if it detects that the first external component is not present.

The Final Office Action notes paragraphs [0084], [0090], and [0092] in Whitehurst, which discuss an implantable system control unit (SCU) 130 and its interaction with an external appliance 220/230 and a “separate or specialized implantable device.” Whitehurst, par. [0090]. Applicants first note that the “separate or specialized” device that can optionally record and telemeter conditions/responses is an implantable device, and thus the combination of the SCU and this device is not the same as a medical device system with an implantable component and an external component configured to be positioned external to the patient body as provided in claim 1.

While Whitehurst does describe an external electronic appliance 230 and an external appliance 220, Applicants respectfully submit that the combination of the SCU and either of these appliances is not the same as the implantable component and the external component provided in claim 1. For example, Applicants submit that Whitehurst does not teach an implantable component configured to operate according to a second treatment therapy mode if it detects the presence of an external component, but stop operating according to the second treatment therapy mode if it detects that the first external component is not present. Although the external electronic appliance 230 can be used to charge or adjust stimulation parameters of the SCU during charging (Whitehurst, par. [0092]), Whitehurst does not discuss the SCU operating or not operating according to a treatment therapy mode based on detecting the presence of the external appliance. Further, functions such as battery charging and algorithm adjustments are not part of a mode for carrying out a treatment therapy, but rather are more akin to maintenance tasks. In addition, Applicants submit that Whitehurst does not disclose an external component generating a signal that is detectable by an implantable component to determine the presence of the external component.

The Examiner recognized the deficiencies of Whitehurst, which Applicants submit also apply to amended claim 1 in addition to the points discussed immediately above. However, Applicants respectfully submit that Terry does not provide the limitations missing from Whitehurst as the Examiner determined. In the Final Office Action, the Examiner focused on Terry’s Figure 3A and column 10. Figure 3A is reproduced below:

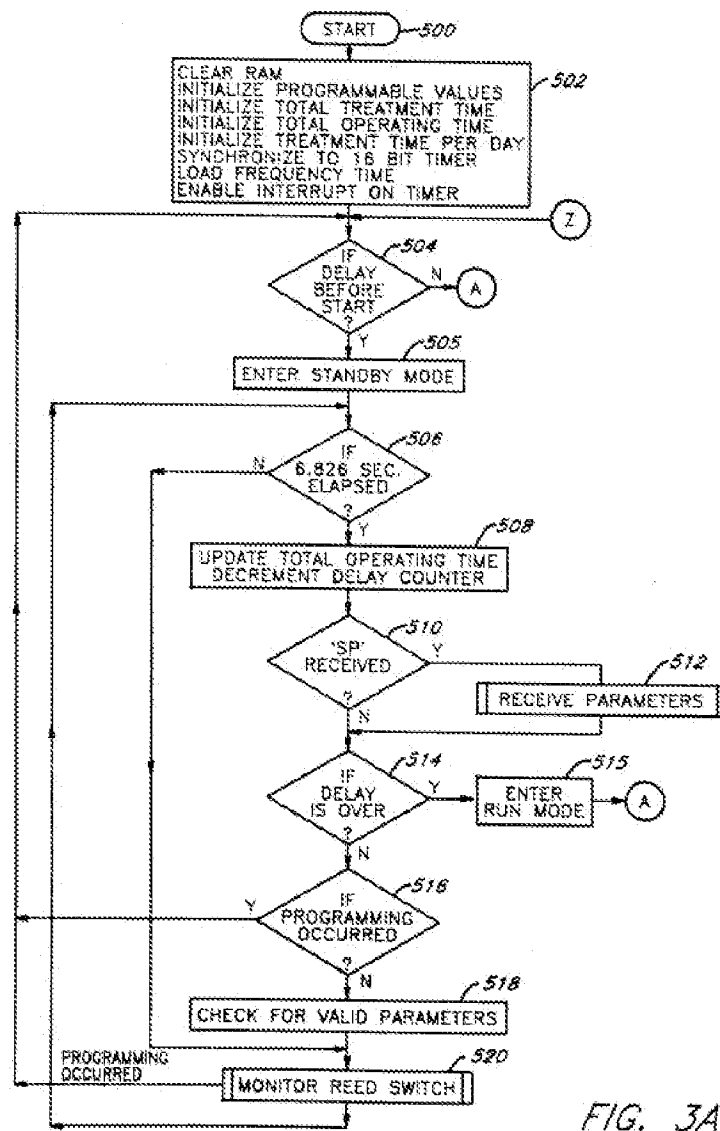


FIG. 3A

The portion of Terry's operating sequence 500 illustrated in Figure 3A appears to Applicants to be little more than an initial delay sequence or standby mode in which the device periodically checks for programmer communications while it waits for the delay to end. Accordingly, Applicants submit that this portion of Terry does not appear to show any indication that the implant is operating according to a treatment therapy mode. In contrast, Figure 3A describes a process that occurs before the implant even enters an active "run mode" designated at 515. The Final Office Action also notes that Terry's implant determines if the external programmer does or does not communicate (allegedly signifying the presence of the programmer, though the Office Action is silent on this point). However, even if Terry detects

the presence of the programmer at 510, there is no discussion of operating according to a second treatment therapy mode based on detecting the programmer as provided in claim 1. Instead, the implant merely receives programming parameters at 512. In addition, as far as Applicants can tell, Terry does not contemplate stopping a second treatment therapy mode based on detecting that the programmer is not present.

Accordingly, Applicants respectfully submit that Whitehurst and Terry fail to teach, suggest, or imply all of the elements of claim 1 for at least the reasons presented above. In addition, Applicants respectfully submit that there would not have been a convincing line of reasoning with a rational underpinning as to why one skilled in the art would have modified the applied references to overcome the deficiencies noted above. Accordingly, Applicants believe claim 1 to be in condition for allowance and respectfully request that the rejection of claim 1 be withdrawn.

Additional Independent Claims and Dependent Claims

Amended independent claims 11, 13, 39, and 40, as well as new independent claim 74 include some limitations in common with independent claim 1, and thus are believed to be patentable over the applied references for at least some or all of the same reasons presented above with respect to claim 1. Claims 2, 3, 7, 8, and 52-58 depend from claim 1, claims 59-72 depend from claim 11, and claims 16-20, 22, 23, 26, 29-32, 34, 45, 51, 73, and 74 depend from claim 13. Thus, these dependent claims are believed to be patentable for at least some or all of the reasons presented above in addition to other grounds based on the specific additional limitations of the dependent claim. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections and allow the claims.

Conclusion

Applicants submit that this application is in condition for allowance for at least the reasons presented above. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Michael J. Feller/

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Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

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